MÁSTER UNIVERSITARIO EN OPTOMETRÍA Y CIENCIAS DE LA VISIÓN

TRABAJO FINAL DE MÁSTER

DIURNAL REGRESSION WITH ORTHOKERATOLOGY LENSES

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Los Srs. Joan Pérez Corral y Genís Cardona Torradeflot como directores del trabajo

CERTIFICAN

Que la Sra. Meritxell Vázquez López ha realizado bajo su supervisión el trabajo "*Diurnal regression with orthokeratology lenses"* que se recoge en esta memoria para optar al título de máster en optometría y ciencias de la visión.

Y para que conste, firmamos este certificado.

Sr. Joan Pérez Corral
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Terrassa, 25 de Octubre de 2018

MÁSTER UNIVERSITARIO EN OPTOMETRIA Y CIENCIAS DE LA VISIÓN

DIURNAL REGRESSION WITH ORTHOKERATOLOGY LENSES

RESUM

Propòsit. L'ortoqueratologia (orto-k) produeix canvis corneals com a resultat de la pressió exercida per les lents de contacte rígides. Aquest estudi pretén aportar més informació sobre els canvis corneals produïts pel tractament d'orto-k després d'una primera nit d'ús.

Metodologia. Quinze subjectes (quinze ulls) van portar lents CRT de Paragon durant una nit. Al dia següent, la curvatura corneal i la paquimetria es van mesurar, a les mateixes coordenades predefinides, a diferents moments (al retirar la lent, i 3, 6 i 9 hores després) amb el topògraf Pentacam.

Resultats. A l'estudi va participar una mostra de 10 dones i 5 homes amb una edat mitjana de 26.10±3.15 i 22.40±1.43 anys, respectivament. A la curvatura corneal anterior i posterior no es van trobar diferències significatives entre les mesures repetides en el temps. En canvi, a la paquimetria es va observar una tendència que indicava que la diferencia més gran es troba entre la mesura prèvia i la primera mesura després de l'ús de l'orto-k.

Conclusions. L'espessor corneal varia amb només una nit de tractament amb orto-k. La curvatura corneal no mostra diferencies estadístiques. Una mostra major es necessària per obtenir conclusions fermes, donada la gran variabilitat inter-subjecte en els resultats.

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DIURNAL REGRESSION WITH ORTHOKERATOLOGY LENSES

RESUMEN

Propósito. La ortoqueratología (orto-k) produce cambios corneales como resultado de la presión ejercida por las lentes de contacto rígidas. Este estudio pretende aportar más información sobre los cambios corneales producidos por el tratamiento de ortoqueratología tras una primera noche de uso.

Metodología. Quince sujetos (quince ojos) hicieron uso de lentes CRT de Paragon durante una noche. Al día siguiente, la curvatura y la paquimetría se midieron en diferentes momentos, en las mismas coordenadas predefinidas (al retirar la lente, y 3, 6 y 9 horas después) con el topógrafo Pentacam.

Resultados. En el estudio participó una muestra de 10 mujeres y 5 hombres con una edad media de 26.10±3.15 y 22.40±1.43 años, respectivamente. En la curvatura corneal anterior y posterior no se encontraron diferencias significativas entre las medidas. En cambio, en la paquimetría se observó una tendencia indicando que la diferencia más grande se encuentra entre la medida previa y la primera medida tras el uso de las lentes de orto-k.

Conclusiones. El espesor corneal varía con solo una noche de tratamiento con orto-k. La curvatura corneal no muestra diferencias estadísticas. Una muestra mayor es necesaria para obtener conclusiones firmes, dada la gran variabilidad inter-sujeto en los resultados.

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DIURNAL REGRESSION WITH ORTHOKERATOLOGY LENSES

SUMMARY

Purpose. The technique of orthokeratology (ortho-k) produces corneal changes as a result of the exerted pressure by the rigid contact lenses. This study aims at gaining a better understanding of the corneal changes produced in ortho-k treatment after the first night of contact lens wear.

Methods. Fifteen subjects (fifteen eyes) worn CRT Paragon lenses for one night. The following day corneal curvature and corneal thickness was measured in different moments at the same predefined coordinates (after lens removal, and 3, 6 and 9 hours afterwards) with the Pentacam topographer.

Results. A sample of 10 women and 5 men with a mean age of 26.10±3.15 and 22.40±1.43 years, respectively, participated in the study. In corneal curvature, anterior and posterior, no statistical differences were found. In contrast, in pachymetry a trend was observed showing the greatest difference between the baseline measure and the first measure after ortho-k lenses use.

Conclusions. Corneal thickness changed with one night of ortho-k treatment. Corneal curvature does not show statistical differences. A larger sample is needed to obtain sounder conclusions given the high inter-subject variability of the results.

Este trabajo está presentado en formato artículo, de acuerdo con las instrucciones escritas para los autores en la revista ***Contact Lens & Anterior Eye***.

La publicación *Contact Lens & Anterior Eye* se encuentra clasificada en la posición 32 (de 59) de la categoría *Ophthalmology* del *Journal Citation Reports*. Se trata de una revista publicada por la *British Contact Lens Association*, con una periodicidad mensual. Su factor de impacto (edición 2017 *JCR*) es de 1.865.

Las instrucciones para los autores se encuentran detalladas en el **Anexo 1**.

Diurnal regression with orthokeratology lenses

Abstract

Purpose. The technique of orthokeratology (ortho-k) produces corneal changes as a result of the exerted pressure by the rigid contact lenses. This study aims at gaining a better understanding of the corneal changes produced in ortho-k treatment after the first night of contact lens wear.

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Conclusions. Corneal thickness changed with one night of ortho-k treatment. Corneal curvature does not show statistical differences. A larger sample is needed to obtain sounder conclusions given the high inter-subject variability of the results.

Key words: Orthokeratology; Myopia; Myopic progression; Refractive error; Corneal refractive therapy; Corneal topography

Acronyms and abbreviations: Ortho-k (orthokeratology); Rigid Gas Permeable (RPG); Intraocular Pressure (IOP); Corneal Hysteresis (CH); Corneal Resistance Factor (CRF); Ocular Response Analyzer (ORA); Central Corneal Thickness (CCT); Manifest Refraction Sphere (MRS); Base Curve (BC); Return Zone Depth (RZD); Landing Zone Angle (LZA); ACA (Anterior Corneal Apex); AC (Anterior Corneal); AC1N (AC 1mm Nasal); AC2N (AC 2mm Nasal); AC3N (AC 3mm Nasal); AC4N (AC 4mm Nasal); AC1T (AC 1mm Temporal); AC2T (AC 2mm Temporal); AC3T (AC 3mm Temporal); AC4T (AC 4mm Temporal); AC1S (AC 1mm Superior); AC2S (AC 2mm Superior); AC3S (AC 3mm Superior); AC4S (AC 4mm Superior); AC1I (AC 1mm Inferior); AC2I (AC 2mm Inferior); AC3I (AC 3mm Inferior); AC4I (AC 4mm Inferior).

1. Introduction

In the last years, myopia has become a health problem worldwide[1]. When myopia appears at young age it has a higher risk to progress into high myopia[1]. East Asian countries have the highest myopia prevalence, about 60-90% of the younger population[1],[2]. Myopia levels have become epidemic. The prevalence in South Korea is 96.5% for the 19 years old boys and, in China, 95.5% for Chinese university students[2]. Myopia progression is associated with an increase in axial length[2]. Because of this, parallel ray beams from infinity converge in a point in front of the retina (*Figure 1*). High myopia can be associated with important ocular diseases and complications[2]. Pathological myopia is ranked second as visual impairment factor globally[3]. Furthermore, myopia is estimated to cost more than 2 billion dollars annually in the United States[3].

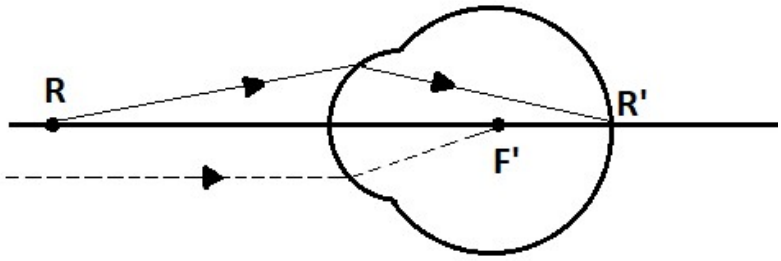

Figure 1. Image of a near and distant object in a myopic eye.

The increased myopia prevalence has led to investigate different strategies to stop myopia progression and to find the best method for myopia correction. These strategies include: the use of atropine drops, the use of bifocal or progressive addition lenses, contact lenses to manipulate peripheral retinal image and ortho-k lenses[2]. Some of these techniques are based in Smith et al.[4] hypothesis about the peripheral retinal image manipulation to inhibit eye elongation[2]. The use of bifocal and progressive addition has shown a small statistical effect[2]. Some studies report that the rates of myopia progression in children wearing ortho-k lenses were about 50% in comparison with children wearing spectacles or soft contact lenses[5].

Orthokeratology is based in rigid contact lenses for corneal reshaping. Corneal reshaping with contact lenses started in the 1960s[5], [6], [7]. These first contact lenses were used during the day and the treatment needed months to be effective[6]. With the new designs, contact lenses are used during the night and the treatment needs less time[3]. Besides, overnight use reduces the initial discomfort with the lenses, also improving lens fitting[6]. Current overnight ortho-k lenses are high permeable rigid gas permeable (RPG) with a “reverse

geometry" design consisting of multiple posterior curvatures and a flatter central radius. These curvatures induce a central corneal flattening[8]. This design improves centration and stability of the lens and leads to more predictable results than initial designs[9]. Orthokeratology lenses commonly cause refractive changes that stabilize after 7-10 nights of use and allow patients to be independent of their habitual correction during the day[8]. The most myopia reduction occurs after the first night of ortho-k use[10]. This myopia reduction is temporary: some patients need to use their ortho-k lenses every night, others do an sporadic use of the lenses[8]. The change in refraction lasts a few hours during the day: J.Walline and co-workers concluded that after 6 hours after lens removal near to 90% of patients had 20/25 of visual acuity without correction[11].

Orthokeratology lens exert positive pressure at the centre of the cornea as well as negative pressure at the mid-periphery. This differential pressure profile induces the usual ortho-k corneal changes. The corneal shape in ortho-k leads to myopia correction because it is known that the cornea contributes about 70% of the refractive eye power[12]. There are some studies about how ortho-k works, but the exact mechanism of this myopia reduction is unclear. The topography of a typical ortho-k user for myopia shows a flatter central zone preceded by a steeper mid periphery[13]. Structural changes, as shown in *Figure 2*, are reflected in the topographical changes of *Figure 3*. Some researchers argue that the tear film has an important role in the pressure forces that lead to the topographic changes[13]. Studies like those of Swarbrick et al. suggest that corneal change was induced by changes in the anterior corneal tissue rather than corneal flexion[14]. Possible mechanisms of corneal changes include: corneal bending, epithelial cell redistribution, epithelial cell compression, cellular compression with intercellular fluid transfer, increased cell mitosis, increased cell retention and stromal remodeling, among others[13]. The accepted theory, which was postulated by Swarbrick et al. describes a central epithelial compression or thinning followed by a mid-periphery epithelial and stromal thickening[7]. Similarly, Alharbi and Swarbrick reported that corneal thinning was epithelial in origin, and mid-periphery thickening that was stromal[10]. In addition, the same authors concluded that central thinning was more marked with overnight use instead of open eye use. In contrast, mid-peripheral thickening is less pronounced with overnight use than with open-eye use[10]. However, Choo and co-workers noted that more investigation is required before fully understanding the actual ortho-k mechanism[13]. Besides, it is critical to know how these changes can affect the health of the cornea and related ocular structures.

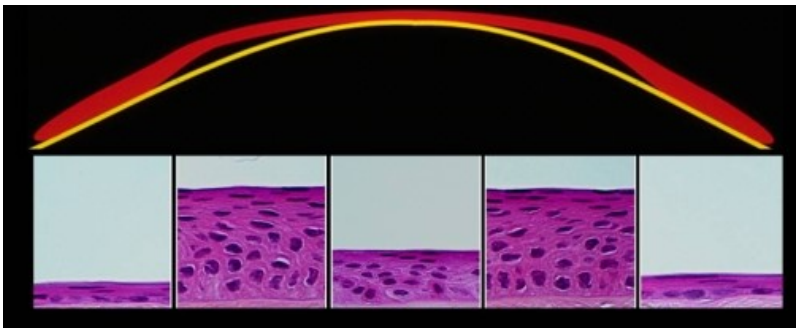

Figure 2. Contact lens and corneal profile showing changes in tissue thickness after lens use[15].

In a study by Poise et al., the authors described a high degree of corneal elasticity or another memory mechanism that causes the cornea to return to the original shape after initial deformation. The lack of persistence in corneal shape helps to understand some of the visual changes that patients experience following lens removal[16].

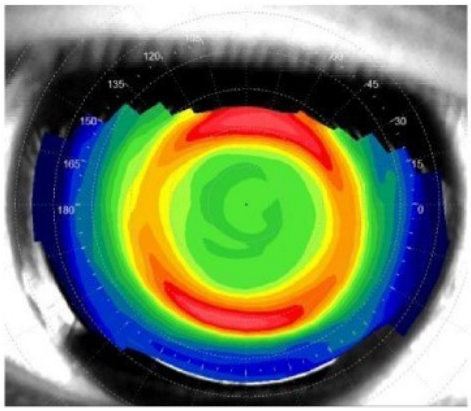

Figure 3. Typical topography following orthokeratology. The red ring denotes a steeper mid-periphery zone, whereas green areas correspond to a flattened central zone[17].

Ruiz-Montenegro et al. found that corneal topography after normal daily lens wear had abnormalities[18]. These abnormalities were more common and severe in rigid contact lenses than in soft contact lenses. Besides, overnight ortho-k has been shown to reduce the optical quality of the eye. Previous studies show that contrast sensitivity function decreases at the same time that high order aberrations (HOA) increase with ortho-k[19]. Other authors have reported reduced optical quality with ortho-k, as measured with a double-pass system[20]. Most parameters return to baseline levels after 1 week of contact lens discontinuation. Furthermore, refractive error and best uncorrected visual acuity need more than 1 week to regress to normality. In the case of refractive error, it needs 2 weeks for a complete recovery.

Overnight use is a good option for better parental supervision in young patients[6]. Sin-Wan Cheung et al. reflects that ortho-k was the most recognized method for myopia control[21]. In addition, between ortho-k, soft contact lenses and spectacles, parents prefer ortho-k treatment[22]. Orthokeratology treatment is safe and it is indicated for low degrees of myopia[13]. Some studies in the last years have shown that overnight ortho-k has an effect in myopia progression reduction[1],[23],[24].

Safety is a critical concern for parents to decide on a possible ortho-k treatment[22]. Indeed, Yue M. et al. conducted a review about the safety of ortho-k lenses including the following aspects: microbial keratitis, corneal staining, tear film stability, epithelial iron deposits, endothelium, corneal thickness and intraocular pressure[3]. Microbial keratitis, which was the main concern, did not present a higher risk in overnight ortho-k than in other overnight lens wear, with no relationship with myopia baseline, age and gender[17]. Risk factors of microbial keratitis were overnight use, reduction in the ocular defences against infection and reduction of epithelial surface integrity caused by reverse geometry designs. However, patients suffering microbial keratitis did not follow any particular pattern. Reneé M. et al. found that 40% of wearers show some type of corneal staining[7]. The frequency and severity of staining increased with ortho-k use, with a direct correlation with the level of baseline myopia. In addition, peripheral punctuate staining was related with pre-existing conditions, and central staining was related with inadequate lens fitting and lens adherence to corneal surface. Regarding the tear film, chronic ortho-k users inform about dry eye symptoms related with a reduced basal tear secretion. Epithelial iron deposit and white lesions were associated with treatment duration. Evidence from a larger sample, showed no significant short or long-term changes in endothelium cell density[3]. Finally, intraocular pressure (IOP), corneal hysteresis (CH) and corneal resistance factor (CRF) decreases in the first week of ortho-k use. After 1 month of treatment, IOP and CH revert to initial values[3].

Corneal biomechanical properties are a key aspect to predict the clinical outcomes of different eye treatments such as ortho-k. Nowadays, there are a limited number of techniques or instruments developed and tested to analyze corneal biomechanics *in vivo*. The main instruments are: the Ocular Response Analyzer (ORA, Reichert, Buffalo, New York, USA), which is based in bidirectional applanation tonometry and the CorVisST (Oculus Optikgërate GmbH, Wetzlar, Germany), which uses Scheimpflug photography. Besides, there is a lack of consensus regarding the best biomechanical parameters to characterize the cornea. Because of this, it is difficult to perform comparative analysis between studies conducted with different instruments or technologies[25]. In consequence, there is a lack of studies about the corneal biomechanical changes induced by ortho-k. In addition, some of these studies were done with a small sample. González-Meijome and colleagues[26], in a

sample including only 8 eyes, concluded that corneal hysteresis has a correlation with changes in the steepest corneal radius and with central corneal thickness (CCT) during lens wear. On the other hand, Lam and Cho, in a sample of 20 myopes, found that corneal resistance factor (CRF) decreased after prolonged lens wear[27]. Thus, short-term ortho-k seems to induce an alteration in corneal biomechanical properties, although these biomechanical changes are two to four times less dramatic than the changes induced by refractive surgery[28].

The objective of the present study was to analyze the diurnal corneal topographic changes induced by overnight ortho-k lens wear. For this purpose, a sample of new patients were fitted with ortho-k lenses and corneal parameters were explored with the aid of a Scheimpflug-based corneal topographer at several instances during the day following overnight wear and lens removal in the morning.

2. Methods

Subjects

Fifteen subjects (10 women and 5 men; mean age 24.9 years; range, 18 to 54) participated in this study. All subjects were free of any ocular or systemic disease and had not worn soft contact lenses for at least 24 hours before enrolling in this study. None of the participants had a previous history of RPG or ortho-k lens wear, nor of refractive or ocular surgery. The purpose and details of the study were explained to the subjects. All subjects signed and informed written consent form (Annex 2). Subjects were treated in accordance with the tenets of the Declaration of Helsinki and data was managed anonymously and only for the purposes of the present study.

CRT lenses

Paragon CRT lenses are designed and manufactured by Paragon Vision Sciences (Mesa, Arizona). The main parameters and characteristics of the CRT lenses used in the study are summarized in *Table* 1. The CRT lens is a highly permeable lens (Dk=100) with HDS100 (pafuflocon D) material approved for overnight wear. Preservative-free solutions were used with the study lenses. Lenses were dispensed with Lacrifresh Moisture tear (AVIZOR®, Madrid, Spain).

Subject	Manifest refraction Sphere (MRS)	Base Curve (BC)	Return zone Depth (RZD)	Landing zone Angle (LZA)	Diameter
1	-2.00D	8.3mm	525µm	33	10.5mm
2	-2.00D	8.6mm	525µm	33	10.5mm
3	-2.00D	8.0mm	550µm	34	10.5mm
4	-2.00D	8.8mm	525µm	32	10.5mm
5	-2.00D	8.5mm	525µm	34	10.5mm
6	-2.00D	8.3mm	525µm	33	10.5mm
7	-2.00D	8.3mm	525µm	34	10.5mm
8	-2.00D	8.5mm	525µm	33	10.5mm
9	-2.00D	8.4mm	525µm	34	10.5mm
10	-2.00D	8.4mm	525µm	34	10.5mm
11	-2.00D	8.7mm	525µm	32	10.5mm
12	-2.00D	8.5mm	525µm	34	10.5mm
13	-2.00D	8.4mm	525µm	34	10.5mm
14	-2.00D	8.5mm	525µm	32	10.5mm
15	-2.00D	7.8mm	550µm	34	10.5mm

Table 1. Parameters of the CRT lenses (Paragon Vision Sciences, Mesa, Arizona) used in the study.

Procedures

Prior to lens fitting, all participants were administered a complete optometric examination, including keratometry and ocular health assessment with the slit-lamp. Contact lenses were fitted to only one eye, selected randomly, of each patient. All procedures aimed at correcting the same amount of refractive error (-2.00 D), irrespective of the actual refractive status of the patients. Lens fitting followed the recommendations of the manufacturer, after which the corresponding fluorescein patterns were evaluated. The flat corneal meridian was used to calculate base curve, return zone depth, and landing zone angle of the lenses. If the fluorescein pattern showed an acceptable fit, the subject slept with the lens for one night for a minimum of 6-7 hours. Patients were instructed to insert the lens just before going to sleep and attend the following day still with the lens to perform the first topography within 5 minutes after lens removal. Corneal topography was measured at baseline (before lens insertion), and the measurements were repeated immediately after lens removal, and 3, 6 and 9 hours later. That is, each patient underwent 4 measurement sessions. In addition, after removing the lens, corneal and conjunctival health were evaluated with a slit-lamp.

Corneal topography

A Pentacam corneal topography system (Oculus, Germany) was used to measure anterior and posterior corneal curvature and corneal pachymetry. The Pentacam system uses a Scheimpflug rotating camera to obtain multiple data

points over 360 degrees, with a capture time of about two seconds[29]. During measurements, another camera monitored minute eye movements to improve image stability. Good inter-observer reproducibility and good intra-observer repeatability have been reported with the Pentacam[29], [30].

Anterior and posterior corneal curvature and corneal pachymetry data were exported in Excel format. Information about age, gender and hours sleeping with the lens were collected. To analyze the different topographic maps a Cartesian coordinate system with the corneal apex as the origin was used. For each exported map the following positions were analysed: the corneal apex, 4 points nasal, temporal, superior and inferior, in 1mm steps. Thus, a total of 17 positions for each map were analyzed. In this way, the exact same positions were analyzed for every subject in each measure.

Statistical Analysis

The statistical analysis of the results was performed with the software IBM SPSS Statistics version 22 and Excel for Windows. First, data was tested for normality with the Kolmogorov-Smirnov test, observing that all parameters were normally distributed. Because of this, in the descriptive analysis, the average and the standard deviation (SD) will be reported, and the inferential statistics will be conducted with parametric tests. Thus, the ANOVA test was employed to analyze the differences between the measurements and, when statistically significant differences occurred, the post-hoc Bonferroni test was used for pair-wise analysis. Preliminary results evidenced a large inter-subject variability in all absolute topography and pachymetry parameters. In consequence, the analysis was repeated by subtracting baseline values from all data points. In all cases, a p-value of less than 0.05 was considered statistically significant.

3. Results

In this study, 15 eyes of 15 subjects (10 women and 5 men with a mean age of 26.10±3.15 and 22.40±1.43 years, respectively) were evaluated. The lenses were used overnight for a mean interval of 7.45±0.19 hours.

The results of the absolute values of anterior and posterior corneal curvature at the different measurement positions and predefined time intervals are shown in *Table 2* and *Table 3*. Similarly, *Table 4* shows the absolute pachymetry values at each position and measurement time.

	Measurement Time				
Measurement position	0	1	2	3	4
Central	7.75±0.22	7.86±0.44	7.90±0.25	7.89±0.24	7.88±0.23
1mm nasal	7.86±0.25	7.95±0.29	7.94±0.20	7.93±0.20	7.93±0.20
2mm nasal	7.90±0.25	7.96±0.25	7.91±0.20	7.89±0.20	7.90±0.22
3mm nasal	8.01±0.24	7.98±0.27	7.94±0.25	7.95±0.24	7.95±0.25
4mm nasal	8.30±2.16	8.26±0.27	8.25±0.24	8.25±0.25	8.27±0.25
1mm temporal	7.81±0.22	7.94±0.40	7.96±0.28	7.96±0.27	7.94±0.25
2mm temporal	7.83±0.20	7.95±0.29	7.93±0.25	7.93±0.24	7.91±0.23
3mm temporal	7.88±0.19	7.94±0.22	7.91±0.21	7.91±0.21	7.90±0.21
4mm temporal	8.00±0.17	7.98±0.19	7.99±0.19	7.99±0.19	7.99±0.18
1mm superior	7.70±0.20	7.82±0.30	7.84±0.22	7.81±0.21	7.82±0.21
2mm superior	7.72±0.20	7.82±0.32	7.77±0.20	7.76±0.20	7.76±0.20
3mm superior	7.79±0.21	7.76±2.02	7.75±0.20	7.74±0.21	7.74±0.19
4mm superior	8.02±2.08	7.98±4.05	7.99±2.82	7.98±2.81	7.97±3.30
1mm inferior	7.69±0.23	7.81±0.42	7.80±0.25	7.80±0.24	7.79±0.25
2mm inferior	7.73±0.24	7.78±0.24	7.75±0.23	7.76±0.24	7.75±0.25
3mm inferior	7.77±0.26	7.76±0.22	7.74±0.24	7.75±0.25	7.75±0.25
4mm inferior	7.91±0.25	7.90±0.25	7.89±0.27	7.88±0.25	7.88±0.25

Table 2. Anterior curvature mean values after one night of ortho-k contact lens wear. Measurements were conducted before ortho-k use (measure 0), 5 minutes after lens removal (measure 1), 3, 6 and 9 hours after lens removal (measures 2, 3 and 4, respectively).

The ANOVA test failed to uncover any statistically significant differences amongst the absolute values obtained at the different measurement times for any of the parameters and positions under evaluation. As noted above, a large inter-subject variability was observed, as reflected by the standard deviation values. Indeed, the actual difference between measurements was smaller than the standard deviation of a single measurement. This could explain the lack of statistical significance encountered by the ANOVA test, which could only be solved with a larger study sample.

In order to reduce the influence of the inter-subject variability, the analysis was repeated by subtracting baseline values from all measurements, that is, by normalizing the results (relative values). The results of the subsequent analysis revealed statistically significant differences among measurement times in relative corneal pachymetry. A graphical representation of the change between successive corneal measurements is shown in *Figure 5* (anterior curvature), *Figure 6* (posterior curvature) and *Figure 7* (pachymetry).

Measurement position	Measurement Time				
	0	1	2	3	4
Central	6.45±0.26	6.38±0.25	6.46±0.21	6.47±0.23	6.49±0.23
1mm nasal	6.64±0.28	6.52±0.26	6.66±0.24	6.66±0.23	6.67±0.24
2mm nasal	6.44±0.26	6.34±0.26	6.46±0.24	6.47±0.24	6.46±0.25
3mm nasal	6.54±0.28	6.53±0.27	6.55±0.26	6.57±0.28	6.57±0.29
4mm nasal	6.90±0.33	6.97±0.36	6.92±0.29	6.91±0.29	6.89±0.31
1mm temporal	6.46±0.28	6.43±0.32	6.49±0.26	6.49±0.28	6.51±0.26
2mm temporal	6.31±0.24	6.29±0.27	6.34±0.24	6.34±0.25	6.34±0.23
3mm temporal	6.47±0.23	6.45±0.22	6.50±0.21	6.50±0.22	6.50±0.21
4mm temporal	6.60±0.24	6.60±0.22	6.63±0.21	6.63±0.21	6.64±0.21
1mm superior	6.16±0.26	6.08±0.25	6.16±0.25	6.17±0.24	6.19±0.26
2mm superior	6.12±0.25	6.01±0.24	6.12±0.25	6.12±0.23	6.13±0.25
3mm superior	6.25±0.23	6.18±1.61	6.25±1.63	6.24±0.24	6.25±0.24
4mm superior	6.73±1.76	6.68±3.45	6.67±3.26	6.66±3.26	6.73±2.80
1mm inferior	6.21±0.28	6.14±0.25	6.17±0.20	6.18±0.25	6.19±0.27
2mm inferior	6.24±0.27	6.17±0.26	6.20±0.25	6.20±0.27	6.21±0.28
3mm inferior	6.29±0.26	6.25±0.25	6.27±0.26	6.26±0.27	6.29±0.27
4mm inferior	6.42±0.27	6.44±0.28	6.41±0.26	6.40±0.28	6.41±0.27

Table 3. Posterior curvature mean values after one night of ortho-k contact lens wear. Measurements were conducted before ortho-k use (measure 0), 5 minutes after lens removal (measure 1), 3, 6 and 9 hours after lens removal (measures 2, 3 and 4, respectively).

Figure 5 shows anterior corneal change between successive measures. At the apex, the greatest difference occurs between the measures 0 and 2, after which the difference decreases. In contrast, temporal measures do not show a clear trend. Regarding nasal relative values, the greatest difference occurs between baseline measures and the first measure after lens removal, with a less pronounced difference towards the periphery. Inferior results show a similar trend to nasal values. Finally, superior differences are more relevant at the 1 and 4 mm positions. Overall, however, no clear trend is discernible in anterior corneal curvature changes after overnight orthokeratology.

Figure 6 shows posterior corneal changes. As in anterior corneal curvature, no marked trend may be observed. Finally, *Figure 7* displays relative corneal thickness data at the different measurement positions and time stamps. In contrast with curvature maps, differences in pachymetry are more pronounced, particularly between baseline and first-hour measurements. This trend may be observed at the different measurement positions. This differences decreases with the time in the same way for the different corneal positions.

It may therefore be concluded that, of the three corneal maps under study, the pachymetry map was the most sensitive to changes following orthokeratology.

	Measurement Time				
Measurement position	0	1	2	3	4
Central	548.5±31.2	566.8±27.6	546,6±28.8	547.1±29.7	544.9±29.7
1mm nasal	562.1±31.4	583.7±28.0	562,6±29.9	563.1±30.4	560.4±30.2
2mm nasal	593.9±33.2	622.6±30.6	596.3±31.8	596.5±32.0	593.5±31.7
3mm nasal	652.3±38.7	685.1±35.0	652.9±35.2	652.1±35.2	649.7±35.6
4mm nasal	731.8±48.5	757.9±46.3	728.0±44.6	726.4±43.4	725.5±44.6
1mm temporal	547.3±31.4	572.6±37.3	544.8±29.3	545.0±30.7	542.9±30.5
2mm temporal	567.6±33.8	590.7±29.3	566.3±30.2	565.9±33.0	563.6±32.6
3mm temporal	610.7±38.7	631.3±34.3	609.0±32.2	608.3±37.4	605.9±36.0
4mm temporal	669.1±47.0	682.8±52.1	663.0±38.3	661.9±45.2	659.0±42.7
1mm superior	565.5±32.6	585.1±26.3	564.2±29.3	564.8±30.6	562.6±31.1
2mm superior	605.3±37.0	631.7±30.5	606.1±33.3	606.4±34.5	604.1±35.9
3mm superior	671.1±43.8	701.4±185.0	672.9±178.0	671.3±39.6	668.7±44.5
4mm superior	757.5±201.3	780.8±403.7	767.4±376.3	769.6±377.6	750.3±315.4
1mm inferior	551.4±29.9	571.3±25.1	551.8±29.0	551.5±29.6	548.9±29.3
2mm inferior	575.1±31.3	598.9±24.5	579.1±31.4	578.5±30.6	575.2±31.7
3mm inferior	620.5±35.9	647.4±28.9	626.7±37.1	626.8±34.0	621.9±36.3
4mm inferior	694.3±41.9	720.3±31.5	699.9±43.4	700.9±40.5	693.2±43.8

Table 4. Corneal thickness mean values after one night of ortho-k contact lens wear. Measurements were conducted before ortho-k use (measure 0), 5 minutes after lens removal (measure 1), 3, 6 and 9 hours after lens removal (measures 2, 3 and 4, respectively).

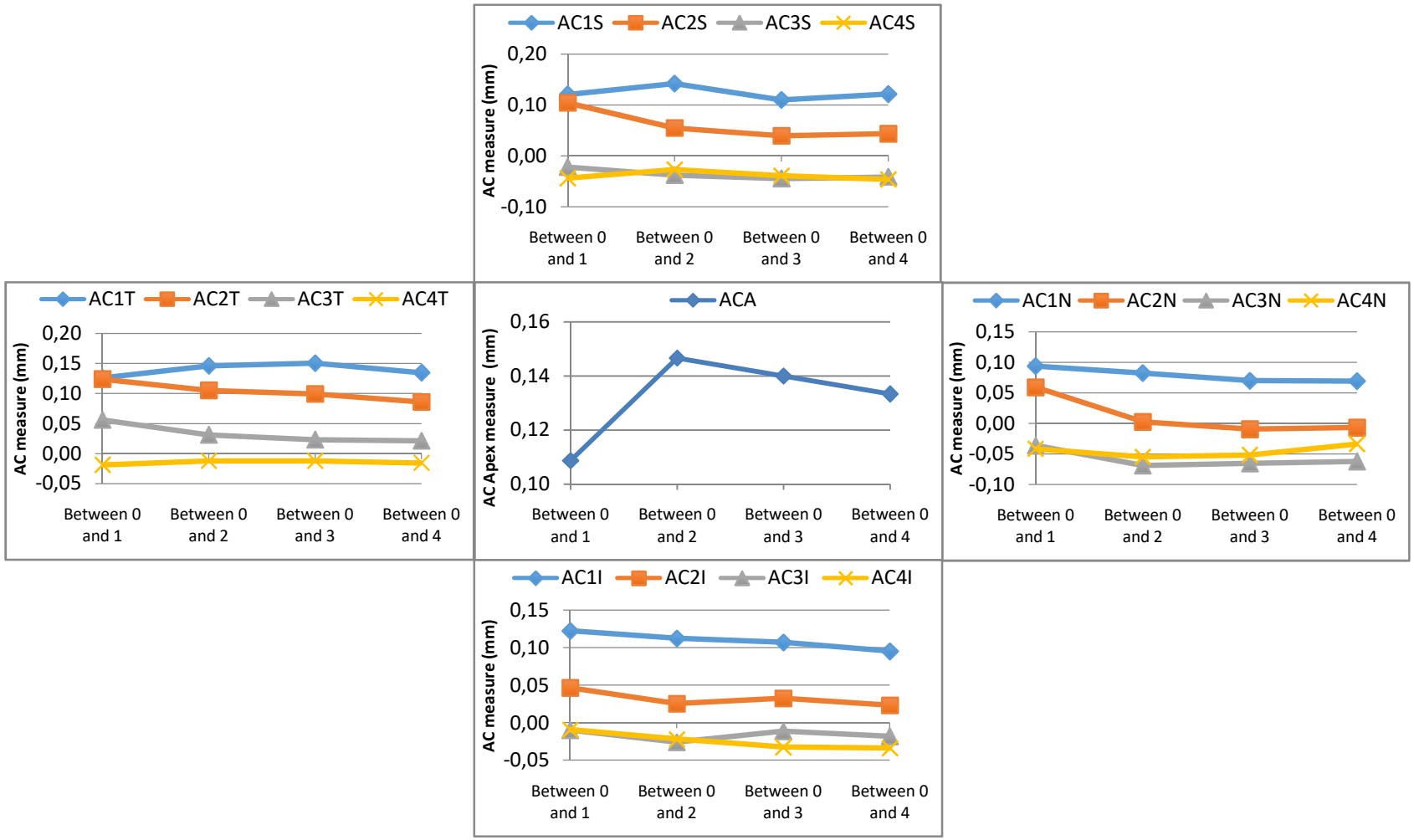

Figure 5. Mean relative differences in anterior corneal curvature after ortho-k lens wear. The different pre-defined corneal positions are analyzed.

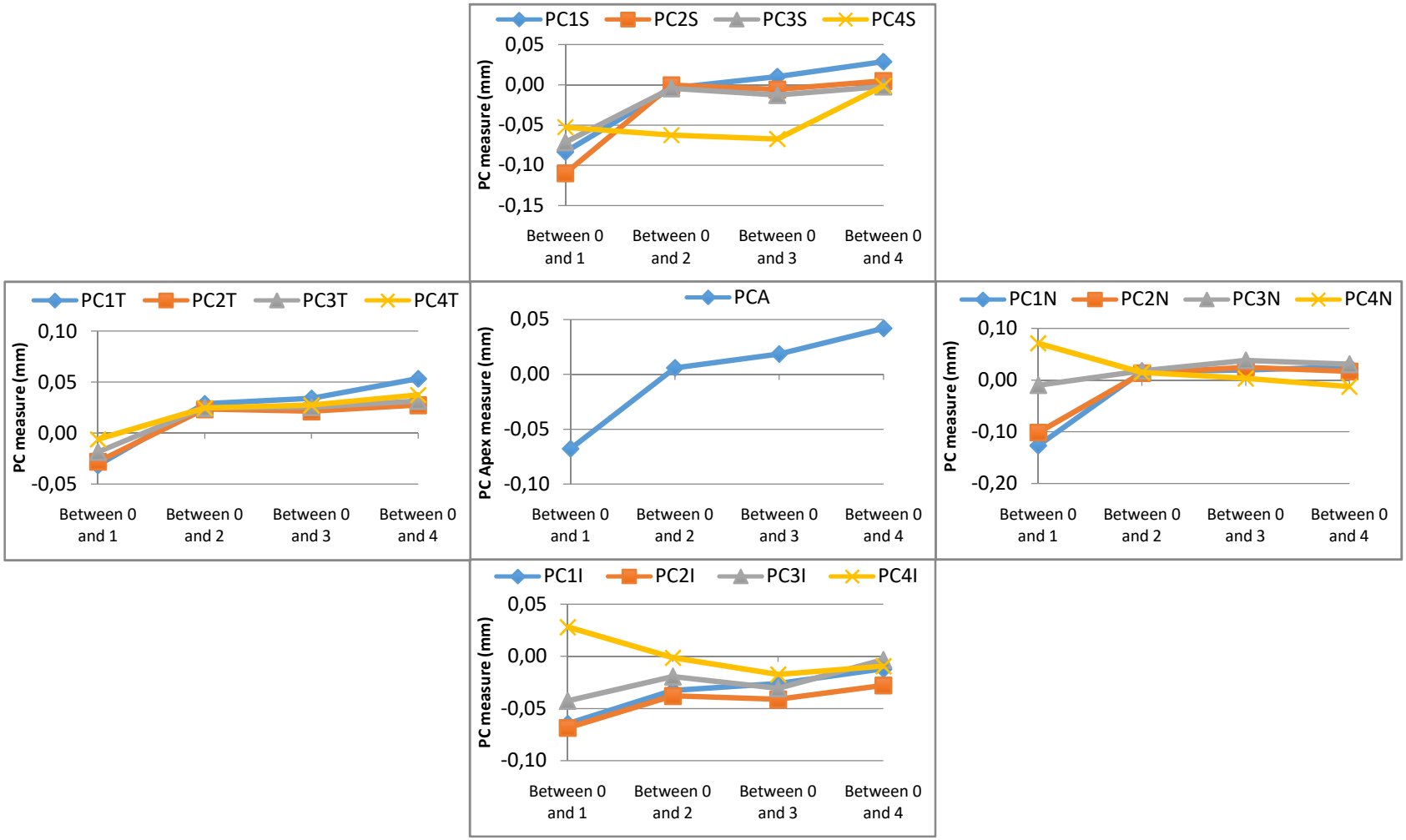

Figure 6. Mean relative differences in posterior corneal curvature after ortho-k lens wear. The different pre-defined corneal positions are analyzed.

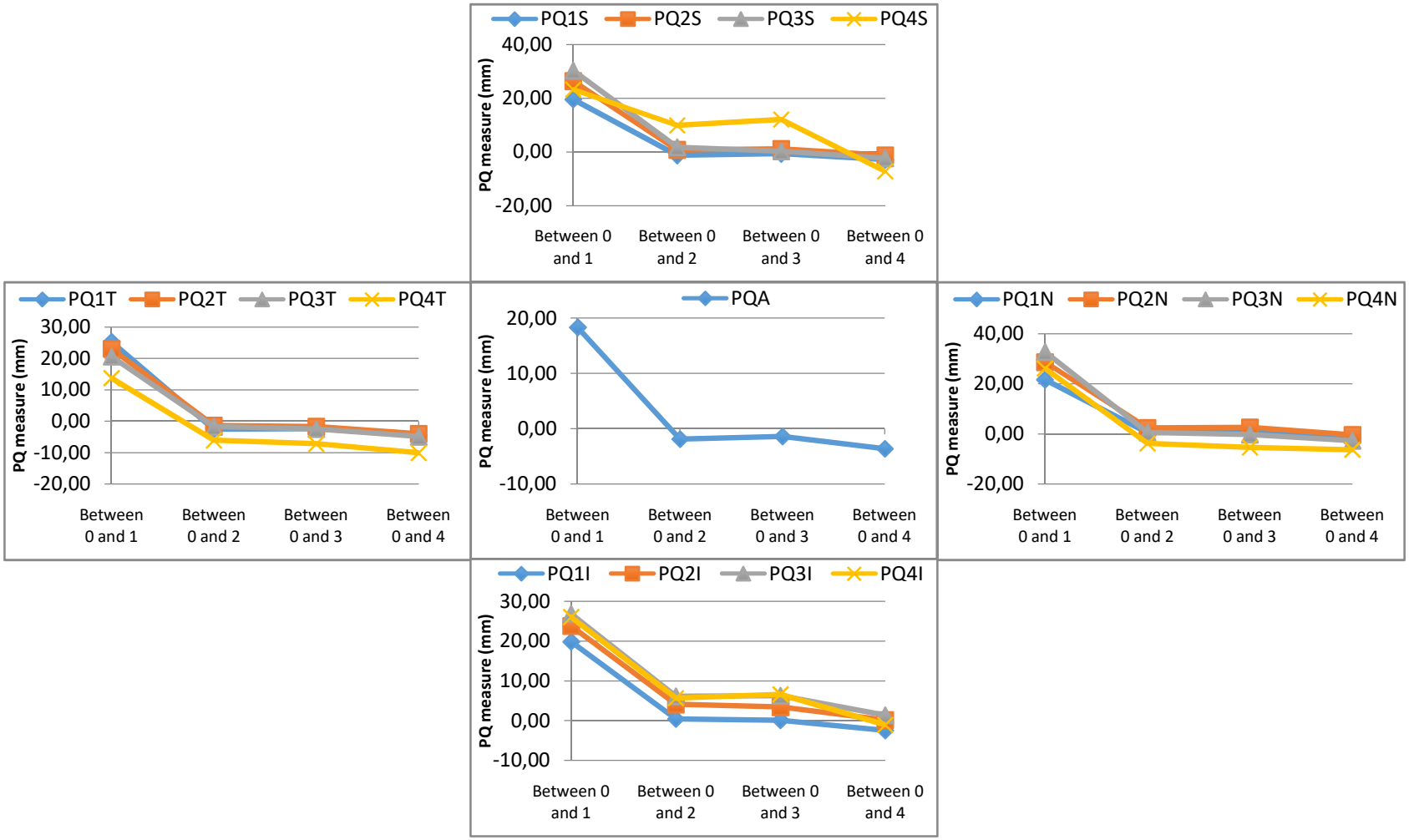

Figure 7. Mean relative differences in corneal thickness after ortho-k lens wear. The different pre-defined corneal positions are analyzed.

4. Discussion

In the present study, the corneal changes after one night of ortho-k treatment were measured. With our limited study sample, inter-subject variability, which was larger than the actual size of the effect under evaluation, did not allow to evidence statistically significant differences between absolute values in anterior and posterior corneal curvature and corneal thickness. A similar absence of differences was found in posterior corneal curvature, in agreement with previous research[31]. In contrast, other studies found differences in posterior corneal curvature, but only at the initial stages of ortho-k treatment[32], [33].

Upon examining relative data, however, a certain trend was observed in corneal pachymetry, not evident in corneal curvature. Thus, relative pachymetry data did show that the greatest corneal thickness change occurred between baseline and the first measure after overnight wear, and later this difference decreased with time. The pachymetry map seems to be more sensitive to detect corneal changes in ortho-k treatment.

Gifford et al., in their study about corneal topographic changes in hyperopic ortho-k, concluded that the changes in hyperopic ortho-k were analogous to myopic ortho-k. Furthermore, the greatest topographic changes occurred during the first night of treatment[34]. Similarly, Soni et al. observed that the cornea can be remodelled within the first 8 hours of overnight exposure, and that corneal curvature changes were apparent immediately after lens removal[35]. This finding is contrary to the data reported in our study, in which corneal curvature changes have not been statistical. This disagreement may be explained by our high inter-subject variability and small sample size, which prevented a more sound statistical analysis.

El Hage and colleagues reported that no change was found in CCT during overnight ortho-k lens wear[36]. These findings are in disagreement with those encountered in this study in which pachymetry was found to be particularly useful to detect changes.

Another study of Soni and colleagues reported that corneal change occurred during the first night and suggested an immediate response to lens wear[37]. In addition, Polse et al. concluded that the cornea shows a high degree of tissue elasticity, which tends to revert changes over time[16]. An interesting addition to this study would be to explore curvature and corneal thickness changes following a longest orthokeratology treatment.

Several studies conclude that CRT lenses are less effective than other lens designs, for instance with regards to DRL lenses (PauneVisión)[38]. This may account for the reduced effect of CRT lenses after one night of treatment observed in our study. Thus, Santolaria et al. found differences between DRL and CRT after the first week of treatment[38], although unpublished work by

other authors describes differences between the these two lens designs after one only night of treatment[39]. Differences between lens designs, study sample characteristics and measurement methodology may also account for discrepancies between our study and previous research. Interestingly, published literature tend to rely on topographic indexes or parameters such as best fit sphere to characterize changes, instead of the predefined local analysis we conduct in the present study.

Another fact to consider is that patients attend in the morning with the lens on their eyes. Physiological oedema occurs overnight as a result of hypoxia. With overnight contact lens wear this oedema may be more pronounced, thus explaining the increase in corneal thickness which was encountered during the first measure, conducted immediately after lens removal. This oedema may have resolved at the time of the second measure in which the corneal thickness was found to decrease. In contrast, previous research commonly measure corneal thickness after a considerable period of time following lens removal, that is, once corneal oedema has probably reached normal values.

Orthokeratology lenses work by suction instead of direct pressure to central cornea. Final flattening can be the result of a steeper periphery with time. For this reason, it is correct to see more increased corneal thickness or corneal curvature in the middle periphery rather than decreased corneal thickness or flattening corneal curvature in the centre after the first night of treatment, as it is seen in the current study[40].

5. Conclusions

The principal conclusion of the present study is that corneal thickness is altered with ortho-k use, even with only one night wearing the lens. The pachymetry changes decreased towards the end of the day, suggesting that the cornea tended to revert to the original shape. Several studies conclude that corneal curvature changes are observable with only one night wearing ortho-k lenses. In our study no statistical changes have been found in curvature. The absence of change may be explained by the combination of a small size of the effect and a high inter-subject variability, which could be solved with a larger sample in a future study. Indeed, future studies are needed with a larger sample with the same characteristics (age, refractive error, ethnic group, among others).

More investigation about the short-term changes in corneal parameters is required to further understand the mechanism or mechanisms underlying the orthokeratology treatment. In addition to topography and pachymetry, an analysis of corneal biomechanics is critical to fully characterize the cornea in orthokeratology, in order to allow practitioners to develop strategies to identify which patients would benefit more from this type of correction.

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ANEXO 1

Normas de estilo de la publicación Contact Lens & Anterior Eye

Figuras y tablas

Las figuras y tablas deben estar incrustadas en el archivo del manuscrito en el punto apropiado. Cualquier figura que no se pueda incrustar en el archivo fuente debe cargarse por separado.

Estudios en humanos y animales

Si el trabajo implica el uso de sujetos humanos, el autor debe asegurarse de que el trabajo descrito se haya llevado a cabo de acuerdo con el Código de Ética de la Asociación Médica Mundial (Declaración de Helsinki) para experimentos con seres humanos. El manuscrito debe estar en línea con las Recomendaciones para la Conducta, Informes, Edición y Publicación del Trabajo Académico en Revistas Médicas y apunta a la inclusión de poblaciones humanas representativas (sexo, edad y etnicidad) según esas recomendaciones. Los términos sexo y género deben usarse correctamente. Los autores deben incluir una declaración en el manuscrito de que se obtuvo el consentimiento informado para la experimentación con sujetos humanos. Los derechos de privacidad de los sujetos humanos siempre se deben observar.

Declaración de interés

Todos los autores deben divulgar cualquier relación financiera y personal con otras personas u organizaciones que puedan influir (sesgar) de manera inapropiada en su trabajo. Entre los posibles intereses contrapuestos se incluyen empleo, consultorías, propiedad de acciones, honorarios, testimonios de expertos pagados, solicitudes / registros de patentes y subvenciones u otros fondos. Los autores deben divulgar los intereses en dos lugares: 1. Una declaración de declaración de interés resumida en el archivo de la página de título (si es doble ciego) o el archivo del manuscrito (si es ciego simple). Si no hay intereses para declarar, indique esto: 'Declaraciones de interés: ninguna'. Esta declaración resumida será finalmente publicada si el artículo es aceptado. 2. Divulgaciones detalladas como parte de un formulario de declaración de interés por separado, que forma parte de los registros oficiales de la revista. Es importante que los intereses potenciales se declaren en ambos lugares y que la información coincida. Más información.

Información esencial de la página de título

- Título. Conciso e informativo. Los títulos se usan a menudo en sistemas de recuperación de información. Evite abreviaturas y fórmulas cuando sea posible.
- Nombres de los autores y afiliaciones. Indique claramente el (los) nombre (s) y apellido (s) de cada autor y verifique que todos los nombres estén escritos con precisión. Puede agregar su nombre entre paréntesis en su propia secuencia de comandos detrás de la transliteración en inglés.

Resumen

Se requiere un resumen conciso y real. El resumen debe indicar brevemente el propósito de la investigación, los resultados principales y las principales conclusiones. Un resumen a menudo se presenta por separado del artículo, por lo que debe ser capaz de ser independiente. Por esta razón, las referencias deben evitarse, pero si es esencial, cite el autor (es) y el (los) año (s). Además, se deben evitar las abreviaturas no estándar o poco comunes, pero si son esenciales, deben definirse en su primera mención en el resumen mismo.

Palabras clave

Entre tres y seis palabras clave deben aparecer debajo del resumen para ayudar a la indexación.

Numeración de páginas y líneas

Las páginas y líneas deben numerarse antes de la presentación.

Ilustraciones electrónicas

Puntos generales

- Asegúrese de usar letras y tamaños uniformes de su obra de arte original.
- Incruste las fuentes usadas si la aplicación proporciona esa opción.
- Intente utilizar las siguientes fuentes en sus ilustraciones: Arial, Courier, Times New Roman, Symbol, o use fuentes que se vean similares.
- Numere las ilustraciones según su secuencia en el texto.
- Use una convención de nomenclatura lógica para sus archivos de ilustraciones.
- Proporcione leyendas a las ilustraciones por separado.
- Ajuste el tamaño de las ilustraciones cerca de las dimensiones deseadas de la versión publicada.
- Envíe cada ilustración como un archivo separado.

Tablas

Cada tabla debe ser inteligible sin referencia al texto. Las tablas deben numerarse con números arábigos en el orden en que se mencionan en el texto. Las notas al pie de página de las tablas se deben dar debajo de la tabla y se debe hacer referencia a ellas con letras minúsculas en superíndice.

Citación en texto

Asegúrese de que cada referencia citada en el texto también esté presente en la lista de referencias (y viceversa). Cualquier referencia citada en el resumen debe darse en su totalidad. Los resultados no publicados y las comunicaciones personales no se recomiendan en la lista de referencias, pero pueden mencionarse en el texto. Si estas referencias se incluyen en la lista de referencia, deben seguir el estilo de referencia estándar de la revista y deben incluir una sustitución de la fecha de publicación por "Resultados no publicados" o "Comunicación

personal". La cita de una referencia como 'en prensa' implica que el artículo ha sido aceptado para su publicación.

Estilo de referencia

Texto: Indique referencias por número (s) entre corchetes. Se puede hacer referencia a los autores reales, pero siempre se deben proporcionar los números de referencia.

ANEXO 2

Consentimiento informado para estudio de la regresión diurna con lentes de Ortoqueratología

Naturaleza y objetivos del estudio:

"Estudio sobre la regresión corneal diurna con lentes de Ortoqueratología."

Objetivo del estudio:

- Analizar los cambios topográficos en pacientes tras una noche de uso de lentes de Ortoqueratología.
- Analizar los diferentes cambios topográficos para entender la regresión diurna de este tratamiento tras la primera noche de uso.

Con el mayor conocimiento sobre la regresión corneal con el tratamiento, este puede ser mejorado o servir para futuras investigaciones, ayudando también a conocer los cambios en la calidad visual de los pacientes.

Duración prevista/estimada de la participación en el ensayo clínico:

Dos visitas. Una primera visita de 20-30 minutos. Una segunda visita con topografías espaciadas en el tiempo.

Procedimiento:

Los pacientes deben acudir un día para evaluar la lente óptima (únicamente para un ojo) y un segundo día tras una noche de uso de la lente, en el cual se realizan topografías espaciadas en el tiempo en el mismo día. Las topografías se realizaran en las siguientes franjas horarias; 9-10h, 12h, 15h y 18h.

Las lentes de ortoqueratología están aprobadas por la FDA (Food and DrugAdministration), son lentes seguras y actualmente comercializadas en España. No han sido descritos riesgos relevantes con un buen uso de la lente. Siempre se deben seguir las instrucciones facilitadas por el optometrista sobre el uso y cuidado de la lente, los cuales se basan en;

- ✓ Utilizar la lente únicamente para el ojo indicado por el optometrista.
- ✓ Utilizar la lágrima artificial facilitada por el optometrista para "rellenar" la lente previamente a insertarla.
- ✓ Insertar la lente justo antes de irse a dormir siguiendo las explicaciones facilitadas verbalmente.
- ✓ Guardar la lente correctamente procurando un buen uso.
- ✓ No exponer las lentes a agua del grifo ni otros productos no facilitados por el optometrista.

Voluntariedad:

Este procedimiento es voluntario. Si se decide no seguir adelante puede retirar su consentimiento informado con total libertad en todo momento.

Confidencialidad:

Los datos de este estudio serán tratados de forma totalmente confidencial y tendrán un uso exclusivamente científico con acceso restringido al personal que lo lleva a cabo.

Persona de contacto:

Meritxell Vázquez

Email: xxxxxxxxxxxx@gmail.com

He leído el documento, entiendo las declaraciones contenidas en él y la necesidad de hacer constar mi consentimiento, para lo cual lo firmo libre y voluntariamente, recibiendo en el acto copia de este documento ya firmado.

Yo, ……....., con DNI ……, mayor de edad o autorizado por mi representante legal, con domicilio en ……....., consiento en participar en el ensayo clínico.

Terrassa, ……. de ……de 2018

Firma del paciente. Firma del informador.